1   DIGITAL PRESCRIPTION CARRIER AND MONITOR SYSTEM

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3   Background of the Invention

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5   Other than surgery, non-invasive manipulation, and

6   nutrition, the major means of treating diseases and medical

7   conditions is by the use of prescribed and over-the-counter

8   drugs. Drugs which can be harmful if misused or abused are

9   usually required by regulation to be prescribed by a

10   licensed physician and dispensed by a licensed pharmacist.

11   A prescription is conventionally a written order or

12   "script" by a physician identifying the medication to be

13   dispensed, the dosage, and the time interval at which the

14   dosage is to be taken, or applied in the case of a topical

15   drug. The identity of the drug may include the brand name

16   or its pharmaceutical equivalent. Dosage may include the

17   concentration or the weight of the tablet or capsule

18   containing the active ingredient and may include special

19   instructions, such as before or after meals, before bedtime,

20   or the like. A total number of dosage units is sometimes

21   factored into the dosage for a given medication. In

22   general, prescriptions are intended to achieve and maintain

23   a desired concentration of a drug within a patient for a

24   selected length of time to treat a medical condition.

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1   One problem with the conventional manner of

2   prescriptions is that they are handwritten on a slip of

3   paper. Although errors in filling prescriptions because of

4   legibility problems are rare, they can occur with

5   potentially serious consequences. A conscientious

6   pharmacist will call the prescribing physician if there are

7   any doubts about the prescription script. Another potential

8   problem is that prescriptions can be counterfeited by use of

9   a physician's prescription forms. This usually occurs only

10   with drugs having an abuse or addiction potential. Another

11   problem is that the benefit of a prescribed drug can be

12   diminished if the patient does not follow the prescribed

13   schedule in taking it.

14   Electronic prescription reminder devices which are

15   programmed with the prescription schedule of one or more

16   drugs are known. Such a device sounds an alarm when it is

17   time to take a medication according to the schedule. Also

18   known are devices which record compliance by the patient in

19   taking a prescription. However, the problems in clearly

20   conveying the prescription information to the pharmacist and

21   prevention of counterfeiting or tampering with prescriptions

22   are not addressed by these devices.

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Summary of the Invention

The present invention provides a method and a prescription carrier apparatus for storing prescription data by a physician and for retrieval by a pharmacist. The carrier data cannot be accessed by the patient; however, the carrier also functions as a prescription reminder for the patient and as a prescription compliance recorder.

The prescription carrier is a device roughly the size of a paging receiver or pager and has a dot matrix liquid crystal display (LCD), an infrared (IR) communications interface, pushbutton keys, a sound alert, and a vibration alert. Internally, the carrier includes a microprocessor, non-volatile memory, a real-time clock/calendar, and interface circuitry to the LCD display, the IR transmit/receive devices, the keys, and the alert devices.

Data access to the prescription carrier is made by way of the IR interface which includes IR receiver and transmitter devices. Such IR interfaces are provided on some laptop computers for communication functions, such as conveying data to be printed to a printer without electrical connection of the laptop to the printer. The IR interface provides for communication with a physician's computer or a

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1 pharmacist's computer, both of which are provided with

2 appropriate software to respectively upload or download

3 prescription and/or compliance data. The prescription data

4 may be in the form of a data record with data fields which

5 can be parsed by software within the prescription carrier to

6 retrieve the name of the medication along with dosage

7 factors and dosage scheduling. The processor within the

8 carrier uses the dosage scheduling data to set up a

9 prescription reminder schedule for each medication in

10 cooperation with the real time clock/calendar and the alert

11 devices. By this means, the carrier alerts the patient each

12 time a dose of the prescription medication is due.

13   The prescription carrier includes a "delay" switch and

14 a "take" switch. The delay switch functions similar to a

15 "snooze" button on a conventional alarm clock. It initiates

16 a delay clock function to alert again at the end of a delay

17 period, for example, of ten or fifteen minutes. Some

18 prescriptions may not allow delays in taking a dose. The

19 take switch is operated when the patient takes a medication

20 upon being alerted to do so and also deactivates the alert

21 device. While operation of the delay switch is not

22 generally recorded, operation of the take switch is recorded

23 as a "compliance" with the prescription. Each compliance

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1　record may include the identity of the medication and the

2　time and date that the take switch was operated. The

3　compliance data can be downloaded by the prescribing

4　physician to compare treatment progress with prescription

5　compliance or to simply determine if the patient has or has

6　not been taking the medication as prescribed.

7　　　　Because allowing the patient access to data within the

8　prescription carrier could result in obvious problems, such

9　access is restricted to the prescribing physician and the

10　pharmacist, or their employees. Access can be restricted by

11　the use of simple passwords. However, the data within the

12　prescription carrier of the present invention is preferably

13　encrypted using one or more encryption keys or digital

14　signatures which are available only to the physician and the

15　pharmacist, but not to the patient. The sciences of

16　effective techniques for encryption of digital data and

17　encryption keys for decrypting are well developed.

18　Background information on such encryption and digital

19　signature techniques can be obtained from U. S. Patent Nos.

20　4,200,770 and 5,537,475, which are incorporated herein by

21　reference. If the present invention, digital signatures

22　incorporating license numbers issued by the U. S. Drug

23　Enforcement Agency (DEA) are preferred.

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Objects and Advantages of the Invention

The principal objects of the present invention are: to provide an improved method and apparatus for conveying a prescription medication from a physician to a patient; to provide such a system including a portable prescription carrier apparatus in which data representing the prescription is uploaded by a physician and downloaded by a pharmacist to fill the prescription; to provide such a prescription carrier apparatus including circuitry and logic which is programmable with prescription data including a prescription schedule for alerting a patient when a dose of a medication is due; to provide such a carrier apparatus which is operable to record compliance of the patient with the prescription for subsequent downloading and analysis by the prescribing physician; to provide such a carrier apparatus which is similar in size and shape to a pager receiver and which includes both sonic and vibratory alert devices; to provide such a carrier apparatus in which prescription data therein is encrypted and which cannot be decrypted by the patient to thereby prevent falsification or counterfeiting of the prescription data therein; and to provide such a digital prescription carrier and monitor

1 system which is economical to manufacture, which is precise

2 and effective in use, and which is particularly well adapted

3 for its intended purpose.

4   Other objects and advantages of this invention will

5 become apparent from the following description taken in

6 conjunction with the accompanying drawings wherein are set

7 forth, by way of illustration and example, certain

8 embodiments of this invention.

9   The drawings constitute a part of this specification

10 and include exemplary embodiments of the present invention

11 and illustrate various objects and features thereof.

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13   Brief Description of the Drawings

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15   Fig. 1 is a front elevational view of a digital

16 prescription carrier and monitor system which embodies the

17 present invention.

18   Fig. 2 is a block diagram illustrating the principal

19 circuit components of the digital prescription carrier and

20 monitor system.

21   Fig. 3 is a flow diagram illustrating the principal

22 software components of the system.

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1 <u>Detailed Description of the Invention</u>

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3   As required, detailed embodiments of the present

4 invention are disclosed herein; however, it is to be

5 understood that the disclosed embodiments are merely

6 exemplary of the invention, which may be embodied in various

7 forms. Therefore, specific structural and functional

8 details disclosed herein are not to be interpreted as

9 limiting, but merely as a basis for the claims and as a

10 representative basis for teaching one skilled in the art to

11 variously employ the present invention in virtually any

12 appropriately detailed structure.

13   Referring to the drawings in more detail:

14   The reference numeral 1 generally designates a digital

15 prescription carrier and monitor device which embodies the

16 present invention. In general, the carrier 1 is adapted to

17 have prescription data uploaded thereinto from a physician's

18 computer for transportation to a pharmacy at which the

19 prescription data is downloaded into a pharmacist's computer

20 and the prescription filled. The carrier 1 is also adapted

21 to provide alerts at times when the prescribed medication is

22 to be taken in accordance with the prescription and to

23 record compliance by the patient with the prescription.

1   The carrier 1 includes an outer housing 2 sized similar

2   to a pager and may include a resilient belt clip (not shown)

3   for wearing the carrier 1 on the belt of a patient or user.

4   The housing 2 includes a dot-matrix liquid crystal display

5   3, operation buttons 4, an alert device selection switch 5,

6   a sonic output device 6, and infrared interface link windows

7   7 and 8. The illustrated carrier 1 includes buttons for

8   scrolling up 14, scrolling down 15, delay 16, take 17, and

9   backlight toggle or light 18. The housing 2 also has a

10   battery (not shown) which powers circuitry 20 (Fig. 2)

11   therein through a low battery detector power supply 21.

12   The circuitry 20 includes a central processing unit or

13   CPU 24 which may be a microprocessor or microcontroller.

14   The processor 24 includes, among other on-chip components,

15   non-volatile RAM memory 26 and a real-time clock/calendar

16   27. Alternative to, or in addition to, the non-volatile RAM

17   26, the CPU 24 may include or be interfaced with read-only

18   memory (ROM) and/or conventional memory or RAM (neither

19   shown). Software 30 (Fig. 3) which operates within the

20   carrier 1 is stored in the non-volatile RAM 26.

21   The operation buttons or switches 4 are interfaced to

22   the CPU 24, as is the LCD display 3. LCD driver circuitry

23   32 interfaces the display circuitry 3 to the CPU 24.

1   Preferably, the display 3 is a dot-matrix type which

2   provides greater flexibility of characters which can be

3   displayed thereon than, for example, 7-segment type

4   displays. The illustrated display 3 may, for example, be a

5   commonly available 16 character by 2 line display. The

6   illustrated carrier 1 includes the scroll buttons 14 and 15,

7   the delay switch 16, the take switch 17, the backlight

8   switch 18, and the alert select switch 5. However, it is

9   foreseen that other user-selected functions may be desirable

10   in the carrier 1, such that the carrier 1 is not intended to

11   be limited only to the switches shown. The backlight switch

12   18 toggles one or more light emitting diodes or LED's (not

13   shown) which illuminate the display 3 to facilitate reading

14   the display in darkness. Although the display 3 is

15   preferably formed using liquid crystal display technology

16   because of its low power consumption and ready availability,

17   other display technologies could alternatively be employed.

18   The carrier 1 is provided with the sonic alert device 6

19   to remind the user that it is time for a dose of a

20   medication, the schedule for which is being tracked by the

21   carrier 1. The sonic alert device 6 may be a small

22   loudspeaker or other audio transducer capable of generating

23   an acoustic signal. The device 6 is powered by sonic drive

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1   circuitry 36 and interfaced to the CPU 24 thereby. The

2   sonic drive circuitry 36 may simply be a power amplifier or

3   may incorporate other elements. The carrier 1 is also

4   preferably provided with a vibrating alert device 38 in

5   cooperation with vibrator drive circuitry 40. Such

6   vibrating alert devices are common in paging receivers and

7   generate a tactile vibration when activated. The alert mode

8   selection switch 5 enables the user to select either the

9   sonic alert 6, the vibrating alert 38, or both. Although

10 not illustrated, it is also foreseen that the carrier 1

11 could be provided with a flashing lamp as an alternative

12 alert device for hearing impaired persons, although such

13 persons would still benefit from the vibrating alert 38.

14   The carrier 1 includes a communication port 42 for

15 interfacing the carrier 1 to an external computer or PC

16 system 44. Such a communication port 42 could be a

17 conventional RS-232 serial port or a more recent

18 communication interface such as a universal serial bus (USB)

19 interface, a "Firewire" (trademark of Apple Computer, Inc.)

20 interface, or the like. In the illustrated carrier 1, the

21 communication port 42 is an infrared (IR) data link 46

22 including a transmitter (TX) channel 48 and a receiver (RX)

23 channel 50. Such IR links 46 are provided on some laptop

1   computers, as well as on some peripheral devices, such as

2   printers, so that a document can be printed from the laptop

3   computer by the printer without a conductive connection. In

4   the carrier 1, the IR port 46 is used to upload a

5   prescription data into the carrier 1 and to download such

6   data from the carrier 1.

7   Fig. 3 illustrates the principal functions of the

8   software 30 which is executed by the CPU 24 of the carrier

9   1. In general, the carrier 1 is able to track the schedules

10   for a plurality of medications, the number of which is

11   limited by the size of the RAM 26, in cooperation with the

12   real-time clock/calendar 27. When a dose of a medication is

13   due, one or both of the alert devices 6 and/or 38 is

14   activated. The user of the carrier 1 can review the

15   upcoming medication schedule on the display 3 using the

16   scroll keys 14 and 15. The prescription data is entered

17   into the carrier 1 from an external computer 44 and accessed

18   to fill the prescriptions by way of the IR data link 46.

19   The external computer 44 executes special software (not

20   detailed herein) to access the carrier 1.

21   Referring particularly to Fig. 3, from the start

22   function 52, when a new battery (not shown) is installed in

23   the carrier 1, a main loop 53 is entered. The main loop 53

1   includes a mode test 54, a scroll test 55, and a dose time

2   test 56. If both scroll keys 14 and 15 are pressed

3   simultaneously, the IR data link 46 is activated at 57 for a

4   selected wait interval, such as 10 seconds. Otherwise, the

5   current time/date is displayed and next scheduled medication

6   to be taken and dose time are displayed, at 58, and the

7   scroll test 55 is entered. If operation of a single scroll

8   key 14 or 15 is detected at 55, the next medication and dose

9   time are displayed at 59. This allows the user to review

10   upcoming medications and schedules by simply scrolling

11   through a list. If no scroll key operation is detected, the

12   CPU 24 checks to determine if a dose of a medication is

13   currently due. If not, the process 30 loops back to the

14   mode test 54.

15   If a medication dose is due at the dose time test 56,

16   an alert mode 60 is entered. In the alert mode, one or both

17   of the alert devices 6 or 38 is activated, depending on the

18   state of the alert select switch 5. The alert can be

19   delayed somewhat depending on the medication involved, by

20   operation of the delay switch 16. The delay switch 16

21   causes the carrier 1 to function similar to an alarm clock

22   with a "snooze" feature. At the end of a delay interval,

23   the alert recurs. However, if the take switch 17 is

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1   operated, at 61, the alert device 6/38 is deactivated,

2   operation of the take switch 17 is recorded, at 62, as a

3   "compliance" with the prescription, and the time of

4   compliance is recorded by the CPU 24 in the RAM 26. After

5   recording compliance at 62, the CPU 24 returns to the mode

6   test 54.

7   When the IR data link 46 is activated at 57, a

8   communication test is run at 64. If a communication link

9   has not been established with an external computer 44 by the

10   end of the wait interval, the IR data link 46 is deactivated

11   and control is returned to the mode test 54. If

12   communications have been established at 64, a security test

13   65 is entered, requiring the entry of a valid encryption key

14   or a password. If the entered encryption key or password is

15   not correct, communication between the carrier 1 and the

16   external computer 44 is disabled at 66 and control is passed

17   to the mode test 54.

18   If the encryption key or password is valid, a

19   communication mode test 67 is conducted to determine if a

20   pharmacy mode 68 or a doctor mode 69 is to be entered. In

21   the pharmacy mode 68, the pharmacist is allowed to access

22   all the current prescriptions, to decrement refill counts of

23   certain prescriptions, and to view patient information which

1   is stored in the carrier 1. The doctor mode 69 includes all

2   pharmacy mode privileges and additionally allows entry and

3   deletion of prescriptions, entry or update of patient

4   information, and access to prescription compliance data.

5   Most states still require the presentation of a

6   prescription form signed by a physician for certain

7   medications, especially those with a high potential for

8   abuse. Prescriptions for other drugs may be "called in".

9   The carrier 1 has utility as a sole prescription carrier or

10   as a digital version of a conventional signed prescription

11   form. The digital prescription data stored in the carrier 1

12   can be uploaded into the pharmacy computer system for

13   inventory control purposes, as well as to reduce data entry

14   errors and for cross-checking purposes. Thus, the carrier 1

15   of the present invention complements the functions of

16   current paper based methods of filling prescriptions rather

17   than simply replacing or duplicating such functions. The

18   carrier 1 also has a reminder function and a compliance

19   recording functions. The data link 46 gives the carrier 1

20   the capability of being accessed remotely, for example over

21   the internet, for the entry or modification of prescriptions

22   by the physician or review of the prescriptions or

23   compliance data by the physician or pharmacist.

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1   It is to be understood that while certain forms of the

2   present invention have been illustrated and described

3   herein, it is not to be limited to the specific forms or

4   arrangement of parts described and shown.

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